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10/825,930	04/16/2004	Robert S. Neuwirth	ABL-101	9014

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EXAMINER

ARNOLD, ERNST V

ART UNIT PAPER NUMBER

1616

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/825,930	Applicant(s) NEUWIRTH, ROBERT S.	
	Examiner Ernst V. Arnold	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 37 is/are pending in the application.
4a) Of the above claim(s) 31-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 24-30 and 37 is/are rejected.
- 7) ☒ Claim(s) 19-23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The Examiner acknowledges Applicants response to the restriction requirement with the election of Group I, claims 1-30 and 37, without traverse and the election of polymeric beads without traverse filed on 12/05/2005. Accordingly claims 1-30 and 37 are presented for examination on the merits. Claims 31-36 are withdrawn from consideration as being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner exactly what substantially spherical means because the specification lacks some standard for measuring the degree intended and, therefore, is properly rejected as indefinite. (See: *Ex parte Oetiker*, 23 USPQ2d 1641 (Bd. Pat. App. & Inter. 1992).)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, 9, 12, 16-18, 24, 25, 28, 30 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Kodama et al. (JP 6-172585).

The Examiner has provided for the Applicant's benefit the English language abstract and machine translation of JP 6-172585. The Abstract DERWENT-ACC-NO: 1994-238910 abstracting JP 06172585A discloses porous 1,2-polybutadiene carrier, formed into pellets, which the Examiner interprets to read upon beads, with silver compounds and/or silver complexes thus reading on instant claims 1, 2 and 30. Blending of the silver based anti-fungal agent and porous 1,2-polybutadiene would inherently have the silver based anti-fungal agent on the surface and within the pellets thus reading on instant claims 8 and 9. The silver compounds include silver nitrate, silver acetate and silver lactate, for example, and thus anticipate instant claims 12, 13, 16, 17 and 18 (Abstract and paragraphs [0009]-[0013]). Among these, koro DAIRU silver has great sterilizing properties and is almost harmless to the body (paragraph [0010]). In addition, sanitary goods can be used with the antibacterial composition ([0023]). The Examiner interprets this to mean that the compositions are suitable for physiological use. The Examiner interprets the 1, 2-polybutadiene carrier to be a

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synthetic polymeric binder that is physiologically tolerable and thus instant claims 24, 25, 28 and 37 are anticipated.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

With respect to the tissue necrosing amount of a water soluble silver ion releasing compound, the Examiner does not have the capacity to test the composition of the Abstract to observe whether or not it will necrose tissue. When the compositions between the prior art and the instantly claimed invention appear to be the same then the burden is placed on the Applicant to demonstrate otherwise.

Claim Rejections - 35 USC § 102

Claims 1-3, 6, 8, 10, 11-13, 24, 25, 26, 28, 30 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsukisaka et al. (JP 05345010A).

The English language Abstract DERWENT-ACC-NO: 1994-039723 abstracting JP 05345010A and the machine translation have been provided for Applicant's benefit.

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The Abstract discloses a porous antibiotic bead with binder. The porous antibiotic bead with binder can be used in sanitary goods, which the Examiner interprets to mean that the beads are suitable for physiological use ([0001]). The bead can contain a water-soluble salt of an antibiotic metal (silver), such as silver nitrate (a water soluble inorganic salt) thus reading on instant claims 1, 2, 12 and 13 ([0013] and [0014]). Styrene beads and polyethylene beads can be used (instant claims 3, 6 and 37). The Examiner interprets perforated polystyrene beads of instant claim 6 to mean porous. The metal is present from 0.01-10 w/w% and the average particle size might be 0.1-10 mm (5 mm is disclosed) and bead size can be easily regulated thus reading on instant claims 10 and 11 (Abstract and [0045]). The binder is distributed on the surface of the bead and represented physiologically tolerable alginic acid, carboxymethyl cellulose (CMC), polystyrene sulphonate, polyacrylate, etc..., thus reading on instant claims 24-26, 28 and 30.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

With respect to the tissue necrosing amount of a water soluble silver ion releasing compound, the Examiner does not have the capacity to test the composition of the Abstract to observe whether or not it will necrose tissue. When the compositions between the prior art and the instantly claimed invention appear to be the same then the burden is placed on the Applicant to demonstrate otherwise.

Claim Rejections - 35 USC § 102

Claims 1-3, 6, 8, 9, 12, 13, 24, 25, 28-30 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirai et al. (US 5,213,895).

Hirai et al. disclose a particle-bearing composite comprising a solid carrier and polymer-protected particles adsorbed thereon (Abstract and column 5, lines 58-62). The solid carrier is preferable porous and made from organic polymers such as polystyrene and have a size of from about 1 micron to about 10 mm, but with no particular limitations, with a spherical or elongated shape (Column 5, lines 35-44 and column 6, lines 1-3 and 29-31). The Examiner interprets this to read upon beads. Hirai et al. disclose a silver particle-polystyrene resin composite bearing 81×10^{-7} mole (as silver atoms) per gram of the polystyrene resin (Column 18, lines 5-9). The Examiner calculates this to represent about 0.87 mg of silver per gram of resin. The resin was made by adding a silver particle dispersion consisting of silver nitrate and poly(N-vinyl-2-pyrrolidone) to a macroporous polystyrene resin (For Applicant's benefit, the Examiner has attached the product information sheet for Bio-Beads SM-2 from Bio-Rad

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Laboratories.) and thereby adsorbing the silver particles onto the polystyrene resin (instant claims 1-3, 6, 8, 12 and 13) (Column 17, Example 15). It is the Examiner's position that the macroporous beads would inherently have at least a portion of the silver within the beads and thus read on instant claim 9. Poly(N-vinyl-2-pyrrolidone) acts a physiologically tolerable binding matrix thus anticipating instant claims 24, 25, 28 and 29.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

With respect to the tissue necrosing amount of a water soluble silver ion releasing compound, the Examiner does not have the capacity to test the composition of Hirai et al. to observe whether or not it will necrose tissue. When the compositions between the prior art and the instantly claimed invention appear to be the same then the burden is placed on the Applicant to demonstrate otherwise.

Claim Rejections - 35 USC § 102

Claims 1-3, 6, 8, 12, 13, 24-27 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Siiman et al. (US 5,552,086).

Siiman et al. disclose silver coated polystyrene beads (Abstract; and column 8, lines 10-18). Siiman et al. disclose that aminodextran coated polystyrene beads were added to a hot aqueous silver nitrate solution with stirring to ultimately form a uniform coating on the beads thus reading on instant claims 1-3, 6, 8, 12 and 13 (Column 12, example 6-column 13, line 28). The Examiner interprets aminodextran to be a dextran and thus anticipate instant claims 24-27.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

With respect to the tissue necrosing amount of a water soluble silver ion releasing compound, the Examiner does not have the capacity to test the composition of the Siiman et al. to observe whether or not it will necrose tissue. When the

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compositions between the prior art and the instantly claimed invention appear to be the same then the burden is placed on the Applicant to demonstrate otherwise.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukisaka et al. (JP 05345010A).

The reference of Tsukisaka et al. (Abstract DERWENT-ACC-NO: 1994-039723 JP 05345010A and the machine translation) are discussed in detail above and that discussion is hereby incorporated by reference.

The Tsukisaka et al. do not expressly disclose that the beads are foamed polyethylene, foamed polypropylene or solid polypropylene.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use solid or foamed polypropylene or polyethylene as a silver ion delivery vehicle and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the Abstract states that polyethylene beads and styrene beads can be used. It is deemed merely a matter of judicious selection of known polymeric materials, which is well within

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the purview of one of ordinary skill in the art. Polypropylene beads are a homolog of polyethylene beads and would be immediately obvious to one of ordinary skill in the art.

"Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teaching of the cited reference.

Claim Rejections - 35 USC § 103

Claims 1, 10, 11 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai et al. (US 5,213,895) in view of Block (Disinfection, Sterilization and Preservation 1977, pages 395-407).

The reference of Hirai et al. is discussed in detail above and that discussion is hereby incorporated by reference.

1. Hirai et al. do not expressly disclose silver covered beads wherein the beads are substantially spherical and have an average diameter in the range of about 1 to about 6 millimeters or the narrower range of about 2 to about 4 millimeters.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make silver covered beads wherein the beads are substantially spherical and have an average diameter in the range of about 1 to about 6 millimeters or the narrower range of about 2 to about 4 millimeters and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Hirai et al. teach that the bead size does not have any limitations and it is within the purview of one of ordinary skill in the art to produce beads of an appropriate size for the application (Column 6, line 3).

2. Hirai et al. do not expressly disclose the delivery vehicle of claim 1 wherein the silver ion-releasing compound is silver nitrate and is present as a composition that comprises at least about 75% by weight silver nitrate (instant claim 19). Hirai et al. do not expressly disclose the delivery vehicle of claim 1 wherein the silver ion-releasing compound is silver nitrate and is present as a composition that comprises at least about 95% by weight silver nitrate (instant claim 20).

Block teaches that a fused composition can be prepared from silver nitrate, hydrochloric acid, salt and potassium nitrate and cast in molds (Page 396, toughened silver nitrate). It consists of 97-98% silver nitrate and the remainder is silver chloride.

The intended use is for the cauterization of wounds and the removal of warts by application with a pencil.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the concentrated 75% or the greater value of 95% silver nitrate composition because Block discloses the higher value in a composition that is designed to stop bleeding and one of ordinary skill in the art would have wanted to stop the bleeding due to menorrhagia.

One of ordinary skill in the art would have been motivated to do this because the silver nitrate would be more effective for cauterization of wounds at this concentration as disclosed by Bock.

3. Hirai et al. do not expressly disclose beads which contain about 20 mg to about 150 mg of silver nitrate per bead or the narrower range of about 50 mg to about 150 mg silver nitrate per bead.

Bock teaches that silver nitrate would be more effective at higher concentrations as is shown in the differences of bactericidal action by doubling the amount of silver nitrate present (Page 398, Table 20-2). Doubling the amount of silver nitrate increases the bactericidal activity by several orders of magnitude after 15 minutes. Block teaches that silver nitrate is a potent antimicrobial agent effective at concentrations as low as 0.5 micrograms per ml (page 398, Table 20-2).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the higher loading of silver nitrate on the beads to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the silver nitrate would be more effective at higher concentrations as is shown in the differences of bactericidal action by doubling the amount of silver nitrate present (Page 398, Table 20-2). Doubling the amount of silver nitrate increases the bactericidal activity by several orders of magnitude after 15 minutes. The adjustment of particular working conditions, (e.g., determining the exact amount of silver required per bead) is deemed merely a matter of routine optimization which is well within the purview of one of ordinary skill in the art.

4. Hirai et al. do not expressly disclose a composition comprising about 5% by weight potassium nitrate.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to form the silver nitrate carrier into beads and to use up to about 5% by weight potassium nitrate to stop the bleeding due to menorrhagia.

One of ordinary skill in the art would have been motivated to do this because Block teaches a silver nitrate composition with potassium nitrate which is used to apply silver nitrate to patients to cauterize wounds. The adjustment of particular working conditions (e.g., using about 5% by weight potassium nitrate) is deemed merely a matter of routine optimization, which is well within the purview of one of ordinary skill in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie

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obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teaching of the cited references.

Claim Rejections - 35 USC § 103

Claims 1, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al. (JP 06172585A).

The reference of Kodama et al. (Abstract DERWENT-ACC-NO: 1994-238910 JP 06172585A and the machine translation) are discussed in detail above and that discussion is hereby incorporated by reference.

Kodama et al. do not expressly disclose soluble silver salts of silver perchlorate, silver permanganate or silver acetate. The Abstract does mention silver sulphate, silver chlorate, silver chloride, silver picrate, colloidal silver, silver salt of carboxylic acid, silver salt of alkyl, phenyl or alkyphenyl ester of phosphoric or phosphorous acid and the translation provides further guidance on the wide variety of silver materials suitable for use in the invention including silver oxide ([0009]-[0014]).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the soluble silver salts of silver perchlorate or silver permanganate in the composition of the Abstract to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the Abstract and the machine translation of JP 06172585A make obvious the use of silver

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materials with oxidant properties (silver chlorate and silver oxide) thus leading one of ordinary skill in the art to readily envision the common reagents silver perchlorate and silver permanganate.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teaching of the cited reference.

Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA



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